

## Tilburg University

### Cardiovascular health

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## Cardiovascular Health: The Importance of Measuring Patient-Reported Health Status

### A Scientific Statement From the American Heart Association

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#### 1. Introduction

The principal goals of health care are to help people “live longer and live better,” that is, to optimize both survival and health. In the American Heart Association’s (AHA) special report, “Defining and setting national goals for cardiovascular health promotion and disease reduction: the American Heart Association’s strategic Impact Goal through 2020 and beyond,” the AHA set the following goal:

*“By 2020, to improve the cardiovascular health of all Americans by 20% while reducing deaths from cardiovascular diseases and stroke by 20%.”<sup>1</sup>*

The emphasis on improving cardiovascular health is laudable, yet it raises the question of how cardiovascular health is best measured. Indeed, the metrics of cardiovascular health have not been well delineated compared with other cardiovascular mortality and morbidity outcomes.

The AHA’s strategic goals primarily focus on ideal health behaviors (eg, not smoking) and ideal health factors (eg, blood pressure control) as metrics of cardiovascular health.<sup>1</sup> Although these are of clear import, they do not directly

address the World Health Organization’s definition of health as “... a state of complete physical, mental and social well-being.”<sup>2</sup> Moreover, the Institute of Medicine identified patient-centered care as 1 of the 6 domains of high-quality health care, wherein patient-centered care supports clinicians in “attending to their patients’ physical and emotional needs, and maintaining or improving their quality of life.”<sup>3</sup> The Patient-Centered Outcomes Research Institute emphasizes the goal of “focusing on outcomes that people notice and care about such as survival, function, symptoms, and health related quality of life.”<sup>4</sup> Recent concepts of value in health care and the “triple aim” center on improving patients’ health and experience with health care while reducing costs; each reinforces the importance of assessing the impact of disease and medical treatment on patients’ functional status and quality of life.<sup>5,6</sup> The definition of health and concepts of patient-centered care directly support the measurement of patient health status as a key metric of cardiovascular health.

Accordingly, the goal of this scientific statement is to review and advocate for patient-reported health status as a measure of cardiovascular health. The present statement defines patient health

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**Table 1. Top Things to Know**

- Improving cardiovascular health is a central goal of cardiovascular care and a specific aim of the American Heart Association's strategic goals; however, measures of cardiovascular health beyond mortality and morbidity outcomes have not been well specified.
- Patient-reported health status, which includes symptom burden, functional status, and HRQL, is an important measure of health.
- Validated patient health status surveys, including disease-specific instruments for patients with cardiovascular disease, allow for the quantification of this critical, patient-centered outcome.
- Cardiovascular patient health status surveys have been used successfully in clinical trials and other research studies to quantify treatment benefits with regard to symptoms, functional status, and HRQL; however, they remain underutilized.
- In addition to cardiovascular disease-specific factors contributing to worse patient health status (eg, amount of angina in coronary artery disease), other key cofactors must be recognized (eg, comorbid depression). There are also special considerations in the measurement of health status in cohorts such as the elderly.
- Patient-reported health status is an independent predictor of subsequent mortality, cardiovascular events, hospitalization, and costs of care. This has potential implications for risk adjustment and targeting of healthcare resources.
- Patient health status data have the potential to inform clinical decision making. In particular, such information can be important for shared decision making.
- Cardiovascular patient health status assessments can facilitate disease surveillance and quantify populations' health for entities such as accountable care organizations but have not yet been incorporated into population health/disease surveillance efforts. The integration of health status into these activities may enhance the patient-centeredness of care and better characterize the impact of healthcare delivery on patient health.
- Additional research is needed to better understand the determinants of patient health status, the effects of interventions on cardiovascular health, and the most effective strategies to incorporate cardiovascular patient health status measurement in clinical practice and disease surveillance.

HRQL indicates health-related quality of life.

status in the context of cardiovascular health and then describes key aspects of patient health status surveys, with an emphasis on currently available cardiovascular disease (CVD)-specific instruments. Subsequent sections synthesize the current literature, providing examples of studies that have used cardiovascular patient-reported health status measures both as outcomes and as independent (predictor) variables. Areas of need for additional research are highlighted throughout. The statement then describes potential uses of cardiovascular patient-reported health status in clinical decision making and population health surveillance, noting barriers that need to be overcome to realize this potential. Ultimately, the present statement is intended to support the AHA's efforts to promote inclusion of patient health status as a measure of cardiovascular health when setting organizational goals and advocating for cardiovascular health (Table 1).

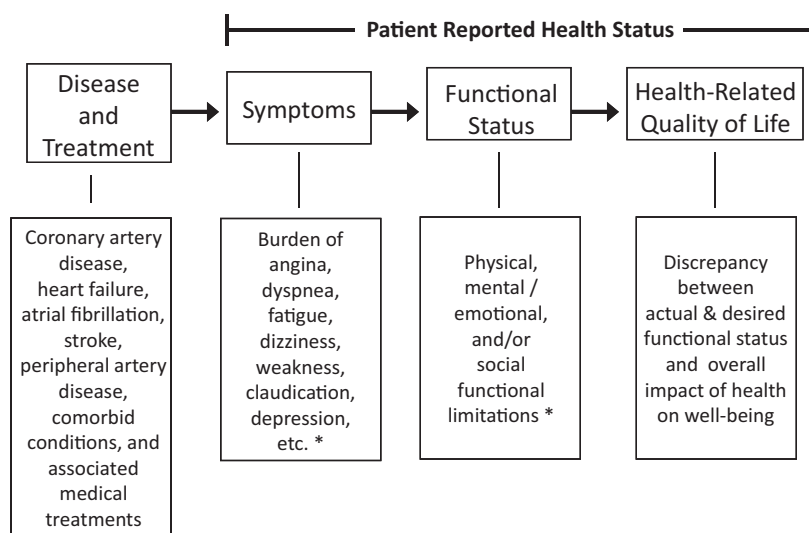
## 2. Executive Summary

Patient health status includes 3 components: symptom burden, functional status, and health-related quality of life (HRQL; Figure).<sup>7</sup> Symptom burden includes the types and frequency

of symptoms a patient may have as a manifestation of disease or from medical treatments (eg, symptoms from side effects of medications). Functional status includes physical, mental/emotional, and social function. Finally, HRQL is the perception of discrepancy between actual and desired functional status and overall impact of disease on well-being for a given patient.

Although there are performance tests that can help quantify physical functional status (eg, exercise treadmill testing), most aspects of patient health status are best captured by patient self-report. HRQL reflects how an individual views and adapts to his or her symptom burden, functional limitations, and prognosis, as well as how patients perceive their overall health. Because each person differentially experiences the degree to which symptoms and functional limitations of disease and medical therapies impact their well-being, HRQL can only be accurately quantified by patient self-report.

An important corollary is that HRQL cannot be accurately inferred by anatomic or physiological tests. Myriad prior studies have shown that measures such as left ventricular ejection



**Figure.** Patient-reported health status. \*From disease or from medical treatments (eg, side effects or complications). Modified from Rumsfeld et al.<sup>7</sup> Copyright © 2002, American Heart Association, Inc. Modified from Spertus et al<sup>8</sup>; reprinted with permission from Elsevier. Copyright © 2002, American Heart Journal. Modified from Wilson and Cleary<sup>9</sup>; reprinted with permission of the American Medical Association. Copyright © 1995, American Medical Association. All rights reserved.

fraction, B-type natriuretic peptide, and extent of coronary artery disease (CAD) by coronary angiography are either weakly or not associated with HRQL.<sup>7,10–13</sup> This is reflected in the experience of most clinicians, in which 2 patients with the same diagnosis and test results (eg, heart failure with left ventricular ejection fraction of 0.30) may have very different symptom burdens, functional capabilities, and quality of life.

To date, the assessment of patient health status in clinical practice has been heterogeneous, largely dependent on communication between clinician and patient in a given episode of care. Although a given clinician may strive to effectively assess the health status of his or her patients, standardized metrics to monitor patient health status over time or to compare among patients are not routinely implemented in practice. Moreover, time constraints may preclude effective assessment of patient health status in a given episode of care, and a given patient may have multiple care providers. In addition, there may be significant discrepancies between provider-assessed and patient-reported health status.<sup>14</sup> Ultimately, each patient is their own “gold standard” for their symptom burden, functional limitations, and HRQL. Thus, there is a clear need for the use of standardized tools to assess patient-reported health status.

Fortunately, valid patient-reported health status surveys, with a basis in the science of psychometrics, have been developed, including disease-specific instruments for patients with CVD. These instruments quantify symptom burden, functional status, and HRQL in a standardized, reproducible, and valid fashion. Patient health status surveys have been used in clinical studies, including randomized clinical trials, to quantify treatment benefits with regard to symptom improvement, functional improvements, and improved HRQL. However, patient health status surveys remain underused as metrics in clinical studies.<sup>15</sup>

In addition, patient health status is a strong, independent predictor of other health outcomes, including mortality, cardiovascular events, hospitalization, and costs of care.<sup>16–18</sup> As such, patient health status surveys not only measure health outcomes, they also help predict outcomes and quantify patient risk above and beyond traditional risk variables such as patient demographics, medical history, and physiological and anatomic tests. Indeed, patient health status surveys are complementary to history, physical, laboratory, and other diagnostic tests. Patient health status may therefore be important for risk adjustment and may be useful in targeting health-care resources such as disease management to those with the largest health deficits.

Although the goal of many therapeutic interventions is to alleviate symptoms, improve functional status, and optimize quality of life, patient-reported health status measures are not used routinely in clinical practice.<sup>7,19</sup> Moreover, patient health status data are not generally available to inform public health or CVD surveillance efforts.<sup>20</sup> HRQL was included as a measure of cardiovascular health in the AHA's strategic impact goals in recognition of the fact that cardiovascular health extends beyond measures of disease prevalence and risk factors to include the impact of CVD on patient functional status and well-being.<sup>1</sup> However, it was listed as a secondary metric of cardiovascular health given the challenges of widespread measurement of HRQL and availability of HRQL data. The

future of patient health status as a measure of cardiovascular health, beyond its use in research, hinges on the degree to which it becomes incorporated in clinical practice and disease surveillance efforts.

### 3. Patient Health Status Surveys

Patient-reported health status can generally be defined as the impact of disease(s) and medical treatments on function and well-being as reported by the patient.<sup>7</sup> More specifically, stemming from the conceptual quality-of-life model proposed by Wilson and Cleary,<sup>9</sup> patient health status has 3 principal components: symptom burden, functional status (eg, physical, mental, social), and HRQL, which reflects how an individual person perceives their functional limitations and overall impact of their health on their well-being.<sup>8,9</sup> The components of patient-reported cardiovascular health status are displayed in the Figure.

Over the past several decades, using the science of psychometrics, multiple standardized patient health status surveys have been developed. Key psychometric properties of these surveys include reliability, responsiveness, interpretability, and validity.<sup>21</sup> The best health status surveys have undergone reproducibility testing (to ensure the survey results are stable when the measure is repeated in a patient in whom health status has not changed), are sensitive to clinical change (ie, the survey scores change appropriately when clinical status changes), and are interpretable (ie, the survey can be scored in a way to quantify patient health status, and changes in survey scores over time are also interpretable).

Of note, there is no true criterion validity for patient-reported health status, because it is not a proxy for other metrics but instead is a direct assessment of the patient's perspective of the impact of disease on their function and HRQL. However, most standardized patient health status surveys have demonstrated predictive or correlative association with other metrics (eg, correlation between patient-reported physical functional limitations and exercise treadmill testing) as part of their development. As a result of this body of scientific work, easily administered and standardized patient health status surveys are available to collect structured information from the patient that cannot be accurately quantified any other way.

Two major types of patient health status surveys are general, or “generic,” and disease specific. General health status surveys quantify overall functional status and well-being but do not ask about symptoms or functional limitations attributable to a particular disease. Perhaps the best-known example, the Short-Form 36, or SF-36 (and the related shorter versions, such as the SF-12), has 36 questions that relate to 8 health status scales (vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning, and mental health) and 2 summary scores (physical and mental component summary scores).<sup>22</sup> Another example, the National Institutes of Health's Patient-Reported Outcomes Measurement Information System (PROMIS), provides online general patient health status surveys to quantify “physical, mental and social well-being,” with branching logic to minimize the number of questions depending on the answers provided.<sup>23</sup> Other general surveys such as the EQ-5D assess patient health utilities

(eg, assigning a number from 0–1 as the personal value of their overall state of health) and thus are particularly useful in the estimation of quality-adjusted life-years in economic analyses.<sup>24</sup> General health status surveys are particularly useful for comparisons among populations (eg, comparing patients with CVD to healthy cohorts or those with other chronic diseases). However, general surveys do not quantify symptom burden (eg, angina) or functional limitations related to CVD and are less sensitive to clinical change (over time or after a therapeutic intervention), and their clinical interpretation is more difficult than that for disease-specific instruments.

Because the present scientific statement is specifically about cardiovascular health, the primary focus here is on CVD-specific patient health status surveys. Disease-specific patient health status surveys quantify symptom burden, functional limitations, and HRQL related to a specific condition. Cardiovascular-specific health status surveys exist for patients with CAD/angina, heart failure, atrial fibrillation, stroke, and peripheral artery disease (PAD). CAD health status surveys have been used in studies of patients with chronic stable CAD, those undergoing coronary revascularization, and after acute myocardial infarction (MI). Heart failure health status surveys have been used in studies of outpatients with chronic heart failure, after hospitalization for heart failure, and among patients with valve disease in which the principal symptomatic manifestation is similar to chronic heart failure (eg, dyspnea). PAD-specific surveys have been used in patients with claudication and critical limb ischemia to determine perceived changes in community-based walking, symptoms, physical and emotional functioning, and quality of life in response to pharmacological, exercise, or revascularization interventions.

Examples of validated CVD-specific patient health status surveys include the MacNew Heart Disease Health Related Quality of Life Questionnaire and Seattle Angina Questionnaire (SAQ) for patients with CAD,<sup>25,26</sup> the Minnesota Living with Heart Failure Questionnaire and the Kansas City Cardiomyopathy Questionnaire (KCCQ) for patients with heart failure or valve disease,<sup>27,28</sup> the Atrial Fibrillation Effect on Quality of Life for patients with atrial fibrillation,<sup>29</sup> the Stroke Impact Scale and Stroke-Specific Quality of Life Scale for stroke patients,<sup>30,31</sup> and the Peripheral Artery Questionnaire and Vascular Quality of Life Questionnaire for patients with PAD.<sup>32,33</sup> Table 2 lists characteristics of some of the currently available and most commonly used CVD-specific patient health status surveys for CAD, atrial fibrillation, heart failure, and PAD.

Given the focus of the present scientific statement, we only listed surveys that capture aspects of all 3 of the principal patient health status domains (ie, symptom burden, functional status, and HRQL) in Table 2. However, there are other validated surveys that capture single domains of patient health status, such as symptom-specific (eg, pain) or function-specific (eg, physical functional status) questionnaires. Well-known examples of the latter include the Walking Impairment Questionnaire for patients with PAD and the Duke Activity Status Index for patients with CAD.<sup>48,49</sup>

The CVD-specific health status surveys listed in Table 2 range from ≈10 to 60 questions. Most emphasize symptoms referable to the given disease (eg, angina in patients with

CAD), physical functional limitations related to those symptoms, and questions about well-being/quality of life. Some include questions about topics such as self-efficacy, mental health status/anxiety, treatment concerns and satisfaction, or sexual functioning. Administration times generally range from 5 to 15 minutes. There are no standard guidelines in choosing one of these instruments over another. The choice will often be driven by the primary condition of interest (eg, heart failure) and may be influenced by factors such as the length and content of the individual surveys or familiarity with an instrument. Often, general and disease-specific health status surveys are administered simultaneously in studies.

Although most of these surveys were designed for patient self-administration on paper, studies using these surveys have also used other modalities such as interview administration (eg, nurse interview of the patient), phone, and Web-based administration. In general, evidence supports that differential modes of administration do not lead to systematic differences or bias in results<sup>50</sup>; however, because these surveys were validated as they are written, 2 issues must be considered. First, when a survey is being administered (eg, read aloud) to a patient, it is important that the questions and the answer choices be read precisely as written. Second, surveys such as those listed in Table 2 were developed and validated by use of formal psychometric testing; any perturbation of the content potentially threatens the underlying validity and reliability. The instruments should be administered and scored in the way they were validated, and it is generally not acceptable to alter the content or order of the existing standardized surveys without further psychometric and clinical validation work to support these alterations. Understanding and addressing potential language or cultural and health literacy barriers to successful administration of health status surveys remains an important area of research. Of note, as listed in Table 2, many of the currently available standardized patient health status surveys have now been translated and validated in a number of other languages in addition to English.

All health status surveys provide a standardized scoring algorithm. In general, there are domain scores (eg, symptom score, physical function score, quality-of-life score) based on answers to questions related to each domain; in addition, for most instruments, a summary score that reflects the overall health status of the patient related to that disease/condition can be calculated. Importantly, a number of the currently available disease-specific health status surveys provide the clinically important difference/change in scores, which facilitates interpretation for use in clinical trials, registries, and clinical practice.<sup>51,52</sup> However, the clinical interpretation of health status survey scores remains a barrier to the use of these instruments in clinical practice and decision making. This is further considered in section 7, “Clinical Use of Health Status Assessments.”

There is no standard of timing of administration of patient health status surveys (eg, when to administer them in relation to a given healthcare episode) nor a standard frequency of repeat measurement. In general, because the surveys were designed to support patient self-administration, a given patient should be in a health state sufficient to answer the questions (eg, not altered or in extremis). That said, patient health status



**Table 2. Characteristics of Some Currently Available Cardiovascular Disease–Specific Patient Health Status Surveys**

Instrument	Population in Which Validated	# of Items Overall	Domains/Subscales (# of Items)	Scoring/Summary Score(s)	Additional Language Versions*	Primary Reference(s)
<b>Coronary artery disease</b>						
Quality of Life after Myocardial Infarction (QLMI-2/MacNew) Questionnaire	Cardiac rehabilitation patients; myocardial infarction patients; angina patients	27	Physical limitations (14); emotional (14); social functioning (13)	Both subscales and summary score are interpreted as scores between 1 and 7; lower scores are better. Minimal significant change score: $\geq 0.5$ for all subdomain scores and summary score.	Chinese Dutch Flemish German Hebrew Hungarian Norwegian Persian Portuguese Spanish Turkish	Valenti, et al <sup>34</sup> (QLMI-2); Höfer et al <sup>25</sup>
Seattle Angina Questionnaire	Patients undergoing exercise treadmill testing; patients undergoing coronary angioplasty; initially stable coronary artery disease patients; coronary artery disease patients	19	Physical limitation (9); angina stability (1); angina frequency (2); treatment satisfaction (4); quality of life/disease perception (3)	Both subscales and summary score are interpreted as scores between 0 and 100; higher scores are better. Significant change scores: Physical limitations change score, $\geq 8$ points; angina frequency change score, $\geq 20$ points; quality-of-life change score, $\geq 16$ points.	>50 Language translations	Spertus et al <sup>26</sup>
Myocardial Infarction Dimensional Assessment Scale (MIDAS)	Acute myocardial infarction patients	35	Physical activity (12); insecurity (9); emotional reaction (4); dependency (3); diet (3); concerns about medications (2); side effects (2)	Subdomain scores are interpreted as scores between 0 and 100; lower scores are better; no summary score	Chinese Turkish	Thompson et al <sup>35</sup>
Cardiovascular Limitations and Symptoms Profile (CLASP)	Chronic stable angina patients	37	Four symptom subscales: angina (5); shortness of breath (5); ankle swelling (3); and tiredness (3). Five functional limitation subscales: mobility (4); social life and leisure activities (3); activities within the home (4); concerns (3); and worries and gender (3)	Unknown range of scores. Symptoms subscales: mild, moderate, severe. Limitations subscales: no limitation, mild, moderate, severe.	Chinese	Lewin et al <sup>36</sup>
Quality of Life Index–Cardiac Version IV (QLI)	CABG patients; patients undergoing PTCA	2×35 Items (satisfaction and importance of quality of life aspects)	Health and functioning (15); socioeconomic (8); psychosocial/spiritual (7); family (5)	Subdomain scores and summary score are interpreted as scores between 0 and 30	French Hebrew Italian Portuguese Russian Spanish Thai Turkish	Ferrans and Powers <sup>37</sup>
<b>Atrial fibrillation</b>						
AF-QoL	Stable atrial fibrillation patients	18	Psychological (7); physical (8); sexual activity (3)	Subscale and summary score are interpreted as scores between 0 and 100; higher score is better; minimal significant change score=12	Spanish	Badia et al <sup>38</sup> Arribas et al <sup>39</sup>
Atrial Fibrillation Effect on Quality-of-Life (AFEQT) Questionnaire	Patients with paroxysmal, persistent, longstanding persistent, or permanent atrial fibrillation	42	Symptoms (5); social functioning (10); physical functioning (9); emotional functioning (7); treatment concerns (8); treatment satisfaction (3)	Subscale and summary score are interpreted as scores between 0 and 100; higher scores are better. Summary score excludes items on treatment satisfaction. Change summary score of 9.8 corresponds to moderate effect size.	French German Italian Spanish Polish Czech Chinese Dutch Korean Norwegian Swedish	Spertus et al <sup>29</sup>

(Continued)

**Table 2. (Continued)**

Instrument	Population in Which Validated	# of Items Overall	Domains/Subscales (# of Items)	Scoring/Summary Score(s)	Additional Language Versions*	Primary Reference(s)
Toronto Symptoms Check List (SCL)	Patients with persistent atrial fibrillation scheduled for DC cardioversion	6	Dyspnea (2); limitations in daily life related to atrial fibrillation (1); discomfort related to atrial fibrillation (1); fatigue related to atrial fibrillation (1); anxiety related to atrial fibrillation (1)	Item-level scores on scale from 0–10. Overall score from 0–60; lower score is better.		Harden et al <sup>40</sup>
Heart failure						
Minnesota Living with Heart Failure Questionnaire (MLHFQ)	NYHA class III patients in a clinical trial with pimobendan	21	Physical (8); emotional (5)	0–105, Best to worst; lower score is better	>30 Language translations	Rector et al <sup>27,41</sup>
Kansas City Cardiomyopathy Questionnaire (KCCQ)	Stable and decompensated heart failure patients	23	Physical limitation (6); symptoms (8); self-efficacy (2); social limitation (4); quality of life (3)	Overall summary score and subscales scored 0–100; higher score is better	>50 Different language translations	Green et al <sup>28</sup>
Chronic Heart Failure Questionnaire (CHQ)	Symptomatic patients with heart failure in RCT of digoxin	16	Dyspnea (5); fatigue (4); emotional (7)	16–122, Worst to best; higher score is better	Chinese	Guyatt et al <sup>42,43</sup>
Quality of Life Questionnaire for Severe Heart Failure (QLQ-SHF)	Patients with NYHA class II/III symptoms in the Metoprolol in Dilated Cardiomyopathy (MDC) trial	26	Psychological (7); physical activity (7); life dissatisfaction (5); somatic symptoms (7)	0–130; Lower score is better	None identified	Wiklund et al <sup>44,45</sup>
Peripheral artery disease						
Peripheral Artery Questionnaire (PAQ)	PAD patients after endovascular therapy; exercise training	20	Most symptomatic leg (1); physical limitations (6); symptom stability (1); symptoms (3); treatment satisfaction (3); quality of life (3); social function (3)	Subscale and summary scores 0–100; higher score is better. Clinically meaningful change=8 points.	Dutch	Spertus et al <sup>32</sup>
Vascular Quality of Life Questionnaire (VASCUQL)	Patients with symptomatic PAD (claudication, ischemic rest pain, tissue loss)	25	Pain (4); symptoms (4); activities (8); social well-being (2); emotional well-being (7)	Subscale and summary score range 1–7; higher score is better	Canadian French Dutch Italian	Morgan et al <sup>33</sup>
Stroke						
Stroke Impact Scale 3.0	Patients with mild and moderately severe stroke	59	8 Domains: Strength (4); memory (7); emotions (9); communication (7); ADL/IADL (10); mobility (10); hand function (4); participation (8); single item: perceived recovery from stroke	Domain scores range: 0–100; higher scores indicate better function. Four physical domain scores can be combined to create a composite physical domain score. Group clinically important difference of the physical domains: Strength=9.2; ADL/IADL=5.9; mobility=4.5; hand function=17.8 points	Italian German	Duncan et al <sup>30,47</sup>
Stroke-Specific Quality of Life Scale	Patients with ischemic stroke	49	12 Domains: Mobility (6); energy (3); upper extremity function (5); work/productivity (3); mood (5); self-care (5); social roles (5); family roles (3); vision (3); language (5); thinking (3); personality (3)	Domain scores range 1–5; higher score represents more normal function. The group clinically important differences of the mobility, self-care, and upper extremity function domains are 1.5, 1.2, and 1.2, respectively.	Danish Spanish German	Williams et al <sup>31</sup>

ADL indicates activities of daily living; CABG, coronary artery bypass graft surgery; DC, direct current; IADL, instrumental activities of daily living; NYHA, New York Heart Association; PAD, peripheral artery disease; PTCA, percutaneous transluminal coronary angioplasty; and RCT, randomized controlled trial.

\*In addition to English.

surveys have been administered successfully in hospital, clinic, and home/community settings, as well as before and after procedures and other healthcare episodes. Some studies, particularly in stroke populations, have used proxy assessments (eg, by spouse/family members) of patient health status.<sup>53</sup> Assessment of health status to evaluate a procedure or to compare therapies or outcomes of care delivery should be performed at “baseline” (ie, before the procedure or the intervention being evaluated) and repeated at some subsequent time point. In general, health status cannot be accurately assessed retrospectively.

#### 4. Health Status Outcomes in Clinical Trial Populations

With increasing recognition of the availability of standardized, validated patient health status surveys as described above, the use of patient-reported health status measures in cardiovascular research is gaining momentum. To date, patient health status surveys have been included in hundreds of cardiovascular clinical studies, including randomized clinical trials, observational studies (eg, prospective cohort studies), and assessments of quality improvement interventions in clinical practice.

Patient health status surveys have been included as outcomes in dozens of clinical trials of cardiovascular therapeutics. Many of these findings have been of central importance to understanding the comparative effectiveness of different care strategies. For example, the PARTNER (Placement of Aortic Transcatheter Valve) trial randomized patients with symptomatic, severe aortic stenosis who were not candidates for surgical valve replacement to transcatheter aortic valve replacement or usual therapy.<sup>54</sup> Patient health status was assessed at baseline and then reassessed at 1, 6, and 12 months with the KCCQ and SF-12. At baseline, mean KCCQ summary scores and SF-12 summary scores were low in both groups, which confirms poor patient health status among patients with advanced aortic stenosis. Although the KCCQ summary score and SF-12 scores improved over time in both groups, the extent of improvement was significantly greater with transcatheter aortic valve replacement therapy than with usual care at 1, 6, and 12 months. Importantly, the differences between groups at each time point during follow-up were clinically and statistically significant. Thus, PARTNER provided strong evidence that transcatheter aortic valve replacement significantly improved the symptom burden, functional status, and quality of life of patients who underwent the procedure.

As another example, the COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation) trial compared a strategy of percutaneous coronary intervention (PCI) with optimal medical therapy to optimal medical therapy alone among patients with stable CAD.<sup>55</sup> Because the goal of PCI among patients with stable coronary disease is to improve symptoms and functional status, rather than improve survival, patient health status was a critical outcome. Patient health status was measured in the COURAGE trial with the SAQ, and patients randomized to PCI had small but significant benefits in terms of less angina frequency, better physical functional status, and better quality of life over 6 to 24 months after randomization; however, health status outcomes were equivalent at 36 months. This highlights that serial

measurement of patient health status can quantify the effects of treatment strategies over time with regard to symptom status, functional status, and quality of life.

In other examples in clinical trial populations, patient-reported health status outcomes have been compared for carotid stenting versus carotid endarterectomy (similar 1-year health status outcomes) and for PCI versus coronary artery bypass graft (CABG) surgery (improvement in health status for both, with small benefits in angina burden for CABG surgery)<sup>56,57</sup>; among patients receiving continuous-flow left ventricular assist devices (significant improvements in health status when preimplantation was compared with postimplantation status at 24 months)<sup>58</sup>; after hospitalization for advanced heart failure (demonstrating a pattern of recovery of health status over 6 months)<sup>59</sup>; among patients undergoing PCI for chronic total occlusions (showing that only patients who are symptomatic at baseline have an improvement in health status outcomes)<sup>60</sup>; in an evaluation of the benefit of exercise training in patients with heart failure (modest but statistically significant improvements in health status with exercise training)<sup>61</sup>; and in an evaluation of surgical ventricular reconstruction in conjunction with CABG surgery along with an economic analysis (no health status benefit for surgical ventricular reconstruction and increased healthcare costs).<sup>62</sup>

Although patient-reported health status surveys are increasingly incorporated into clinical trials, they remain underused.<sup>15</sup> When they are included, it is often only as secondary measures or as “add-on” substudies, akin to cohort studies embedded within clinical trial populations, and are thus frequently only collected on a subset of the overall clinical trial population. Given that a primary goal of many medical therapies is to improve symptoms, functional status, or HRQL, stronger consideration of patient health status as a primary study outcome is warranted. Similarly, “health delivery research” will often use randomized designs to evaluate care-delivery strategies or comparative effectiveness in clinical practice.<sup>63</sup> Improving patient health status will be a primary goal, and thus should be a primary outcome, of many of these studies.

#### 5. Health Status Outcomes: Observational Studies and Special Populations

Patient health status surveys have been collected in a sizeable number of observational (eg, prospective cohort and cross-sectional) studies. Although a comprehensive review of this literature is beyond the scope of the present scientific statement, studies capturing patient-reported health status in cardiovascular populations have evaluated (1) patient characteristics associated with health status, ranging from demographic factors, cardiovascular history and severity of disease, and coexisting medical conditions; (2) patient health status before, during and/or after cardiovascular therapeutic interventions such as PCI or cardiac rehabilitation; (3) psychosocial and behavioral factors and patient health status among patients with CVD or those undergoing cardiovascular procedures; and (4) patient-reported health status as a predictor of other health outcomes such as mortality.

As examples of observational study findings, a number of studies have measured patient health status outcomes after acute MI. These studies found that 1 in 5 patients had angina 1 year after acute MI, and residual or recurrent angina was



associated with worse functional status and quality of life, as well as worse patient satisfaction.<sup>64,65</sup> In addition, potentially modifiable factors such as smoking and depression were associated with patient-reported angina burden after acute MI.<sup>64</sup> Also, older patients, despite a higher mortality, had lower symptom burden and better HRQL at 1 year after MI than younger patients.<sup>66–68</sup>

Overall, there is a surprising paucity of research on the determinants of patient health status outcomes. Examples from existing studies demonstrate that the strongest predictors of improvement in patient health status are informed by baseline health status assessments. Specifically, those having the largest improvement in angina status after PCI had a higher preprocedure angina burden.<sup>69</sup> A recent study evaluated predictors of the combined end point of mortality or persistently low health status after heart failure hospitalization.<sup>70</sup> Predictor variables included low baseline health status (KCCQ score), high B-type natriuretic peptide, hyponatremia, tachycardia, hypotension, absence of  $\beta$ -blocker therapy, and history of diabetes mellitus and arrhythmia. Of interest, predictor variables for persistently low health status outcomes were different from predictors of mortality and readmission.

Future research is needed in the development of risk models and clinical prediction tools for patient health status outcomes in cardiovascular populations. It is hoped that modifiable factors predictive of patient health status can be targeted for interventions; however, formal evaluation of the incorporation of these risk tools in clinical practice will be necessary to demonstrate whether their use can improve patient outcomes. Section 7, “Clinical Use of Health Status Assessments,” provides further discussion of the integration of patient health status measures in clinical practice, including limitations of evidence in this regard to date.

The following subsections summarize the literature among populations that have been key foci for patient health status research, including health status and comorbid depression, health status in the elderly, health status and sex, and health status and race/ethnicity and socioeconomic status. Future research directions are highlighted. Section 6, “Health Status as a Predictor of Other Health Outcomes,” separately considers patient health status as a predictor of outcomes.

### 5.1. Health Status and Depression

Multiple studies have evaluated depression and other factors such as anxiety and posttraumatic stress disorder in relation to patient health status outcomes in cardiovascular populations. The majority of the currently available literature focuses on depression and health status in cardiovascular populations. Depression is prevalent in cardiovascular populations;  $\approx 20\%$  of CAD patients have moderate to severe depressive symptoms.<sup>71,72</sup> Depressed patients have more frequent angina, more physical limitations, less treatment satisfaction, and worse quality of life than nondepressed patients. Among patients with a similar burden of inducible ischemia, current anxiety and depressive symptoms are associated with more frequent angina.<sup>73</sup> Similar findings are present among patients who have experienced an acute coronary syndrome.<sup>74,75</sup>

Among patients with heart failure, the prevalence of depression is even higher (eg, 30% to 35%).<sup>76,77</sup> Depressive symptoms are a strong predictor of declines in health status

among outpatients with heart failure.<sup>77</sup> Similar associations between depression and patient health status have been found in patients with atrial fibrillation and PAD.<sup>78,79</sup> In contrast, traditional cardiac disease severity indices (eg, left ventricular ejection fraction, myocardial ischemia) are only weakly associated with patient-reported health status.<sup>10–13</sup> Also, depressive symptoms are associated with less of a health status benefit with revascularization and predict which patients will show no improvement in functional status 6 months after CABG surgery, which highlights depression as a cofactor in the evaluation of treatment recovery.<sup>79,80</sup>

The sum of literature to date supports that depression is common in cardiovascular populations and is strongly associated with worse patient health status, above and beyond traditional cardiac or clinical variables.<sup>81</sup> As such, studies of patient health status in cardiovascular populations, and particularly evaluation of interventions aimed at improving patient symptoms, functional status, and quality of life, should assess patients for depression. Depression evaluation, with the specific goal of identifying patients for whom depression treatment may be indicated, is an actionable goal for improving health status. Additional research is also needed to identify strategies to incorporate depression and patient health status assessment in clinical practice, to improve patient outcomes (section 7, “Clinical Use of Health Status Assessments”).

### 5.2. Health Status and the Elderly

The elderly are the fastest-growing segment of the population, and CVD is a leading cause of morbidity and mortality in older people. The presence of significant comorbidities, cognitive dysfunction, poor social support, and diminished functional status influences both decision making and treatment outcomes. Health status assessment is therefore particularly important in this population.

As noted previously, elderly survivors of MI experience better quality of life than younger MI patients. It was also demonstrated that age was not associated with functional decline after MI, which addresses potential assumptions related to the association between chronological age and health status.<sup>68</sup> Studies specific to revascularization procedures also suggest that age alone is not a contraindication to treatment. The only randomized trial of invasive versus medical therapy in elderly patients with CVD (the Trial of Invasive Versus Medical Therapy in Elderly Patients [TIME]) used health status as the primary end point and found that patients  $>75$  years of age benefit more from revascularization than from optimized medical therapy.<sup>82</sup> These findings are complemented by other studies that showed improvements in health status after CABG surgery and PCI in elderly patients undergoing these procedures.<sup>83–85</sup>

Patient health status data specific to the elderly for other cardiovascular conditions are more limited. However, the elderly are well represented in studies of transcatheter aortic valve replacement for severe aortic stenosis, in which significant, persistent improvements in quality of life after this procedure over baseline have been demonstrated.<sup>54</sup> It is notable, however, that in cohorts such as that in the PARTNER trial, elderly patients were able to complete the KCCQ, and the KCCQ was sensitive to change with the procedure and was useful in evaluating patient health status among elderly patients over time.<sup>54</sup>

Conventional aortic valve replacement and other isolated cardiac surgeries are also associated with sustained improvements in health status among patients selected to undergo the procedure.<sup>86</sup>

Medical decisions in older patients can be difficult. Frailty, a phenotype of vulnerability to stressors and reduced reserves, is an important concept that can encompass comorbidity; physical function; physiological reserve; social, cognitive, and psychological issues; and nutritional status.<sup>87</sup> Frailty is prevalent among elderly patients with CVD and is associated with adverse outcomes.<sup>87–89</sup> Although not generally included in risk assessment models, frailty has been shown to add significant incremental risk information beyond other clinical variables.<sup>88</sup> This frail phenotype may either be driven by underlying heart disease, and thus potentially may be amenable to improvement by cardiac therapies, or it may be related primarily to noncardiac diagnoses, with only minor contribution from underlying cardiac disease. In the latter case, there may be little to no benefit from cardiovascular interventions and substantially greater concerns about medication or procedural safety.

To date, few studies have focused on frailty and patient health status in cardiovascular populations. Not surprisingly, existing studies support that patient health status is lower among patients with frailty. This suggests another potential utility of health status surveys in capturing additional dimensions of risk (ie, risk related to the contribution of frailty to lower functional status). Further health status research in the elderly should include the design and validation of instruments that can better delineate frailty as a component of health status.

### 5.3. Health Status and Sex

In general, women with CVD have poorer health status than men, even after adjustment for baseline risk factor differences, according to both general and disease-specific assessments.<sup>90–98</sup> These differences can be found within 1 month after an acute MI, as well as over the longer term.<sup>92–94</sup> Women treated with CABG surgery, despite recovering similarly to men, also have impaired health status compared with men at both 6 and 12 months postoperatively.<sup>95,96</sup> Sex differences in health status have also been reported in heart failure and adult congenital heart disease populations.<sup>97,98</sup> The determinants of health status also appear to differ between the sexes. Psychological stress and lower social supports are particularly important cofactors among women.<sup>99</sup> However, sex differences in health status remain despite adjustment for baseline risk factors, depression, and social support. Gender roles and perceptions are a pivotal area for future research.<sup>100</sup>

### 5.4. Health Status and Race/Ethnicity and Socioeconomic Status

Most health status data are from white patients, but some information is available for other races and ethnicities. For example, the Medical Expenditure Panel Survey assessed general health status surveys in the general population.<sup>101</sup> Blacks and Hispanic subjects with coronary heart disease had significantly worse health impairments than whites. Greater anginal symptoms and functional impairment (as measured by the SF-36 and SAQ) were noted among black patients with CAD compared with whites in a cohort of patients undergoing

cardiac catheterization.<sup>102</sup> In patients with diabetes mellitus and CAD enrolled in the BARI 2D study (Bypass Angioplasty Revascularization Investigation 2 Diabetes), clinical symptoms influenced self-reported health status among whites more than blacks, who were already more likely to rate their overall health as poor.<sup>103</sup> Similarly, blacks had more angina, worse quality of life, and worse physical functioning (as measured by the SAQ and the SF-12 physical component summary) than white patients 1 year after an acute coronary syndrome.<sup>104</sup> However, in a more recent evaluation of outcomes after acute MI, observed differences between black and white patients in mortality, rehospitalization, angina burden, and quality of life were no longer significant after risk adjustment for both baseline patient characteristics and site of care.<sup>105</sup> In blacks with advanced, decompensated heart failure, ethnicity was not associated with HRQL, but depressive symptoms were associated with functional impairment.<sup>106</sup> Interestingly, Hispanic patients with heart failure were found to have better health status outcomes than both blacks and whites, which suggests cultural differences may be at play.<sup>107</sup> An important consideration is the validation of the health status tool in that population and the impact of language barriers. Further work needs to explore important health status differences among ethnic groups, using tools with comprehension and cultural tailoring, to determine the racial and ethnic influences on treatment outcomes.

Lower socioeconomic status is associated with worse health status, perhaps as a marker of lessened ability to understand, access, afford, and communicate with the healthcare system. In CABG patients, those who experienced difficulties affording care reported a worse health status on undergoing CABG and 6 months after the procedure.<sup>108</sup> These results were replicated in 2 cohorts of outpatients with heart failure. Difficulties in obtaining affordable health care were associated with worse health status at baseline and at 1-year follow-up compared with those who did not report such difficulties,<sup>109</sup> and the perception about whether patients' income met their demands was independently associated with lower health status scores in another cohort of outpatients with heart failure.<sup>110</sup>

Patient health status differences noted by race, sex, age, comorbidity, and socioeconomic status underscore the varied reasons a particular individual may perceive their health state differentially from others. These findings may also help identify specific interventions to improve health status in key subgroups at risk.

## 6. Health Status as a Predictor of Other Health Outcomes

Although itself an important health outcome, patient health status is also an independent risk factor for other health outcomes, such as mortality. This section summarizes the literature on patient health status as a risk factor for subsequent patient outcomes, as well as potential implications with regard to risk adjustment and targeting of healthcare resources.

Dozens of studies have shown that patient health status measures are strong, independent predictors of subsequent mortality. This is the case both with general health status measures and with disease-specific health status measures. As examples, scores on the SF-36 are independently predictive

of mortality after CABG surgery,<sup>111</sup> scores on the SAQ are predictive of both subsequent acute coronary syndrome and mortality,<sup>112</sup> and scores on the KCCQ, as well as changes in score on the KCCQ (ie, a decline of  $\geq 5$  points between assessments), are predictive of mortality and hospitalization.<sup>113</sup> KCCQ scores are also predictive of resource use and costs among patients with heart failure.<sup>18</sup> There has been a paucity of research examining the association between patient health status and costs of care among cardiovascular populations; this is an area of interest for future research.

Of note, patient health status is predictive of other health outcomes, including mortality, after adjustment for a broad array of more traditional patient demographic, clinical history, physiological, and disease severity variables. The magnitude of association between patient health status and mortality varies depending on the specific health status instrument/survey used, but in many studies, patients with lower health status have at least twice the risk of subsequent adverse outcomes, above and beyond their other demographic and clinical characteristics.

As a corollary, longitudinal patient health status assessments can help identify patients with changes in health status, which may be useful for clinical monitoring.<sup>51,113</sup> For example, patients with heart failure and stable health status may need less frequent office visits for titration of medications or additional testing. However, if a given patient has a significant decline in health status, they are at elevated risk for an adverse outcome and should be evaluated for the cause of the increase in symptom burden or decline in functional status or HRQL. Of note, the effectiveness of such potential clinical practice applications of patient health status are unproven and an ongoing focus for quality of care and outcomes research; patient health status in clinical practice is further considered in section 7, "Clinical Use of Health Status Assessments."

The body of evidence supporting patient health status as an independent predictor of health outcomes has potentially important implications for risk adjustment. Current clinical risk models and quality and performance measures do not include or adjust for patient health status. Most clinicians will endorse that decisions about clinical therapeutics are often related to a patient's functional status. Indeed, clinical impressions of a patient's functional capacity, frailty, and "wellness" often contribute to decision making. Yet these are nonstandardized impressions and have not been quantified with standardized tools. Patient health status surveys are standardized metrics and are predictive of subsequent outcome. Thus, a strong argument can be made for the collection of patient health status information to quantify this risk and for clinical quality and performance measures to incorporate patient health status measures as part of risk adjustment. Without this, clinicians and hospitals caring for patients with worse health status may not have their case mix appropriately accounted for in judgments of their quality of care.

Finally, because patient health status is a risk marker for adverse outcome (mortality and morbidity) and healthcare costs, it may be useful in targeting healthcare resources. For example, it may be effective to target interventions such as case management, disease management, cardiac rehabilitation, home health, or telehealth to patients with low or

worsening health status. The effectiveness and cost-effectiveness of targeting health care resources on the basis of patient health status remains unproven, however.

## 7. Clinical Use of Health Status Assessments

Health status measures have high potential to enhance clinical care.<sup>7,19</sup> To conceptualize the potential role of disease-specific health status measures, a useful analogy is to consider them as a standardized history that reproducibly assesses patients' symptoms, functional status, and quality of life. In much the same way as echocardiography standardized the assessment of left ventricular function, compared with the apical impulse, S<sub>3</sub> gallop, and carotid upstrokes, health status surveys can provide a more precise estimate of a patient's health status at a point in time, as well as track changes over time. Within this framework, patient health status measures have the potential to support clinical care, evaluate healthcare quality, quantify an important component of procedural appropriateness, identify patients for prognostic discussions, and serve as a foundation for shared medical decision making. These potential applications are discussed below, including barriers that must be overcome and additional research needed to fulfill this potential.

An important aspect is the clinical interpretation of patient health status survey results. A number of the validated health status surveys have determined clinically important changes in survey scores. For example, the minimal clinically important score change for the KCCQ is 5 points, with 10- and 20-point changes reflecting moderate and large clinical changes, respectively.<sup>51</sup> In the Eplerenone Post-AMI Heart Failure Efficacy and Survival Trial (EPHESUS), even after multivariable adjustment for a wide array of clinical variables, each 5-point decline in the KCCQ Overall Summary Score on serial assessments was associated with a hazard ratio of 1.11 (95% confidence interval, 1.05–1.17) for subsequent cardiovascular death or hospitalization.<sup>113</sup>

Studies like this suggest how patient health status survey scores may be used for clinical monitoring and prognosis; however, significant barriers remain. There must be clinical familiarity with and understanding of health status survey scores and changes in scores (analogous to laboratory test results). Then there must be guidance on linked clinical actions to improve patient health status, as well as how to weigh the health status results alongside other clinical metrics. The interpretation and use of patient health status survey results in clinical care is a top priority for both research and quality improvement efforts, with linked formal evaluation of interventions that use patient health status information in clinical care.

Unfortunately, formal evaluations of the use of patient health status measures to support clinical practice are limited, and the few studies that have evaluated their use to inform care have not demonstrated improved outcomes.<sup>114</sup> However, a nurse practitioner–led angina clinic in which the SAQ was used as a foundation for titration of antianginal medications was able to demonstrate significant improvements in patients' health status compared with those patients before enrollment in the clinic and compared with other angina patients managed with routine clinical care.<sup>115</sup> Although more research is needed, assessing patient health status as part of clinical care, training clinicians in the interpretation



of health status data, and creating treatment protocols for optimizing patients' health status are potentially important strategies for improving care.

There is evidence that there is great variability in the symptom control and quality of life of patients across primary care providers. In a national study of outpatients in Australian general practitioner clinics, the proportion of each physician's patients who reported weekly or greater angina varied substantially.<sup>116</sup> Among 207 practices, 14% had no patients with weekly angina, whereas in 18% of the clinics, more than half of the patients reported weekly angina, and in 4%, all of the patients reported weekly angina. Importantly, most clinicians believed that angina was optimally controlled in their patients, which highlights the value of directly assessing health status from patients.

To support the routine use of health status as a marker of healthcare quality, the American College of Cardiology/AHA/Physician Consortium for Performance Improvement created performance measures for the routine assessment of patients' health status in CAD and heart failure.<sup>117,118</sup> In recent updates, these entities continued to endorse the assessment of health status as a performance measure for public reporting and included the results of these assessments as a quality improvement measure. As clinicians begin using these measures more routinely, and as tools to simplify their collection, scoring, and reporting, such as patient-oriented medical records, evolve, they will have great potential to help quantify and improve healthcare quality.

The importance of measuring patient health status is underscored by the recent development, measuring, and reporting of appropriate use criteria for coronary revascularization.<sup>119</sup> Given that a primary purpose of coronary revascularization is to improve patients' health status, clinician-assessed Canadian Cardiovascular Society classification is an important element in defining the appropriateness of a procedure. A national study found that among PCIs performed for stable angina, ≈12% were classified as inappropriate.<sup>120</sup> However, Canadian Cardiovascular Society classification has just 4 categories of angina burden, there is interoperator variability in assigning Canadian Cardiovascular Society classification class, and some have raised a concern that clinicians may feel pressured to report higher Canadian Cardiovascular Society classification classes for their patients to justify appropriateness.<sup>121</sup> Use of a patient-reported health status measure is more discriminative for angina burden and less subject to "gaming" and may reduce variability in health status assessment across practices. Moreover, as suggested by the Australian study referenced above, patient-reported health status can also be assessed in outpatient clinics to identify potential underuse of revascularization in symptomatic patients.<sup>116</sup>

As discussed in section 6, "Health Status as a Predictor of Other Health Outcomes," patient health status measures are prognostic of health outcomes. Patient health status assessments can serve 2 purposes in this regard. First, risk stratification is a cornerstone of cardiovascular care, and higher-risk patients are often eligible for more aggressive therapy, such as revascularization in coronary disease or defibrillators in the setting of heart failure. Another important application of patient prognosis is to be able to communicate to patients

their expected outcomes so that decisions regarding desired therapies can be solicited. For example, a prognostic model for patients admitted to the hospital that predicts the combined end point of death or persistently poor health status within the 6 months after discharge was developed recently.<sup>70</sup> The knowledge, for example, that a patient had a >50% chance of dying or never regaining a good quality of life over the next 6 months could prompt proactive discussions between patients and their providers about patient preferences for advanced heart failure treatments (eg, left ventricular assist devices or transplantation) or more palliative, symptom-directed care. The potential role of patient health status survey data in relation to clinical decision making, including palliative care decisions, is an important area for additional research.<sup>122</sup>

Beyond the communication of prognosis, there is potential to use patient health status as a foundation for shared medical decision making in treatment decisions. The field of comparative effectiveness research is designed to examine patient factors associated with treatment outcomes. When the outcome of interest is mortality, the prognostic association of health status with survival may support, with additional research, a more accurate assessment of a patient's anticipated survival and how that might change as a function of alternative treatments. When the outcome of interest is health status, the provision of estimates of health status benefits with different treatment approaches may inform the patient's decision making. For example, the benefits of PCI as a supplement to medical therapy alone in the COURAGE trial were greater for those with worse baseline health status and not significant in those without angina or physical or quality-of-life impairments before treatment.<sup>55</sup> As prediction models are developed for health status outcomes, as currently exist for mortality, these can be deployed to support discussions with patients about treatment options.

For the potential clinical and quality-of-care applications to become realized, practical methods are needed to collect, score, and interpret patient health status data. These operational issues are increasingly addressable in the era of patient engagement, advancing health information technology, and healthcare reform. First, patients are increasingly engaged in their health care and the healthcare system, as evidenced by entities such as the Patient-Centered Outcomes Research Institute (<http://www.pcori.org>), the National Quality Forum (<http://www.qualityforum.org>), and Patients Like Me (<http://www.patientslikeme.com>). Each emphasizes the importance of measuring and improving patient functional and quality-of-life outcomes.

Second, advances in health information technology promise increasing access to electronic data, which can include standardized patient survey data. For example, tablet computers or computer kiosks can be used to collect patient health status data at the time of a visit (eg, in the waiting room). Moreover, the broad availability of computers, Web access, and mobile applications on smartphones support the potential for patients to complete surveys untethered to specific episodes of care/visits; for example, patients may be prompted by e-mail messages with links to the survey or interactive Web programs. Expansion of patient health records may be an important mechanism for patient-driven recording of standardized health status, which

can then be made available to care providers or healthcare entities (eg, hospitals or health systems) or for clinical registries or research at the patient's discretion. In all electronic formats, the surveys can be scored with results immediately available, and these formats support the ability to track over time.

Third, multiple aspects of healthcare reform may support the assessment of patient health status data as part of clinical care and population health management. Currently, there are no direct incentives in the healthcare system for the collection or use of patient health status data. However, trends in healthcare reform promise an emphasis on patient-centered outcomes, assessment and promotion of patient well-being, and shared decision making, with an emphasis on the impact of potential therapies on outcomes including quality of life.

Despite these promising trends, the optimal methods of collection and integration of patient health status data into clinical practice remain undefined, and whether such integration improves patient outcomes remains unproven. As such, this is a top priority for quality improvement and outcomes research. Many of the same questions regarding application of patient health status data in clinical practice are applicable to the potential role of patient health status in population health and disease surveillance.

## 8. Health Status and Disease Surveillance

Patient health status surveys should be considered for inclusion in national surveillance of heart disease and stroke to ensure that the surveillance accounts for cardiovascular health as reflected in these patient health status assessments.<sup>20</sup> Although patient health status measures have been included in research, they have generally not been implemented for cardiovascular surveillance. Surveys by entities such as the Centers for Disease Control and Prevention have addressed health behaviors and risk factors but have not explicitly measured patient health status. Patient health status is an essential measurement for adequate assessment of the impact of heart disease and stroke, as well as of the therapies and interventions for these conditions, on patients' lives. Future efforts toward the establishment of national surveillance for heart disease and stroke should incorporate patient health status assessment and thereby directly promote patient-centered care of the highest quality.

The implementation of health status measurement in disease surveillance, although critical, will be challenging. The widespread use of any instrument raises the issue of reliability and validity across populations and cultures. Although many of the currently available patient health status surveys have been used in various populations, and some have been validated in multiple countries, their utility when collected over time in large populations to inform disease surveillance still needs to be evaluated. Health literacy is also a potential barrier to capturing patient health status on a truly representative scale. In the setting of established CVD, health literacy is associated with adverse outcomes.<sup>123</sup> Thus, additional research is needed to evaluate the optimal methods of using patient health status for disease surveillance, including addressing barriers such as health literacy.

Another important aspect is choosing the patient health status instrument(s) for disease surveillance. As discussed in section 3, "Patient Health Status Surveys," health status

surveys can be general or disease specific, and the selection of the instrument is important to consider with regard to the population(s) intended for assessment. General instruments have the advantage of broad applicability and allow cross-disease comparisons with the trade-off of less specificity and less sensitivity to clinical change over time. Disease-specific instruments are reflective of key symptoms (eg, angina burden for patients with CAD) and are sensitive to clinical change but are not easily comparable across different disease populations, and they are not applicable to patients without extant CVD. Therefore, strategies for effective disease surveillance using patient health status instruments will need to tailor the surveys to intended population(s).

Similar to the discussion of capturing patient health status for clinical care (section 7), advances in patient engagement, health information technology, and health policy should increasingly support the operational aspects of collecting patient health status for disease surveillance. Currently, integrated health systems such as the Veterans Health Administration, Kaiser Permanente, and Intermountain Health may be best positioned to implement the operational infrastructure to capture patient health status for clinical care and population health and then contribute these data to disease surveillance efforts. Because many aspects of healthcare reform are aligned to move the larger US healthcare system toward integrated models of care, larger portions of the system may become better positioned to routinely capture patient health status data.

For example, in "accountable care organizations," groups of providers organized in an accountable care organization receive a share of the savings obtained by providing more efficient and effective care.<sup>124</sup> A fundamental expectation is the tracking of outcomes of system reform in terms of quality health care at the population and community level, as well as individual patient satisfaction. The ability to track outcomes is limited by the lack of tools to measure the effect of care at a population or even community level. In addition, there are few systems in place that document patient health status over time and across organizations. Commitment to an accountable care organization will require a common set of quality metrics that include measures of patient health status and the information technology resources and tools to collect data and provide seamless data flow.

One potentially important approach to capturing patient health status for population health/disease surveillance and clinical care efforts is to leverage existing national cardiovascular clinical registry programs, such as Get With The Guidelines (<http://www.heart.org>), the Society of Thoracic Surgeons National Database (<http://www.sts.org>), and the National Cardiovascular Data Registry (<http://www.ncdr.com>). Although this will take a commitment to expand the operational infrastructure of these programs, the basic infrastructure for clinical data collection with standardized data elements and a national data repository with quality-of-care assessment already exists. One program, the Transcatheter Valve Therapeutics registry (<http://www.ncdr.com/TVT>), has recently committed to capturing the KCCQ at baseline and follow-up along with other clinical registry data for transcatheter aortic valve replacement procedures. Moreover, some health systems are already moving to integrate the data capture for



national clinical registry programs as part of routine workflow, as well as capturing patient-reported measures (eg, via mobile applications). This is one model by which patient health status data may be collected to support clinical care and population health/disease surveillance.

## 9. Conclusions

Patient-reported health status is an important cardiovascular health outcome that includes 3 domains: symptom burden, functional status, and HRQL. Patient health status is also predictive of other health outcomes, including mortality, cardiovascular events, hospitalization, and costs of care. As such, patient health status is important both as a risk factor and a health outcome. Standardized cardiovascular patient health status surveys have been developed and used successfully in

clinical trials and observational studies. Yet these validated measures remain underused as measures of cardiovascular health in research settings. Cardiovascular patient health status measures may also inform clinical decision making, target healthcare resources (ie, to those with low or worsening health status), and enable accurate surveillance of disease burden. To date, this potential has not been realized. The present scientific statement provides an overview of the measurement of patient-reported health status, studies in cardiovascular populations, and future directions for research and reviews the current state and key needs for clinical and surveillance uses of cardiovascular patient health status. This statement advocates for the broader inclusion of patient-reported health status as a key measure of cardiovascular health in clinical research, clinical practice, and disease surveillance.

## Disclosures

### Writing Group Disclosures

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Debra K. Moser	University of Kentucky	NIH†	None	None	None	None	On advisory board for American Image Management*	None
Véronique L. Roger	Mayo Clinic	None	None	None	None	None	None	None
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John A. Spertus	Saint Luke's Hospital of Kansas City	ACCF†; AHA†; Amgen†; Bristol-Myers Squibb/Sanofi†; Cordis†; Eli Lilly†; EvHeart†; NHLBI/NIH†	None	None	None	Copyrights to Seattle Angina Questionnaire, Kansas City Cardiomyopathy Questionnaire, and Peripheral Artery Questionnaire†; Health Outcomes Sciences†	Gilead*; Quest Diagnostics*; St. Jude Medical*; United HealthCare*	None
Mark D. Sullivan	University of Washington	None	None	None	None	None	None	None
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This table represents the relationships of writing group members that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all members of the writing group are required to complete and submit. A relationship is considered to be "significant" if (1) the person receives \$10 000 or more during any 12-month period, or 5% or more of the person's gross income; or (2) the person owns 5% or more of the voting stock or share of the entity, or owns \$10 000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

\*Modest.

†Significant.

## Reviewer Disclosures

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Kathleen Grady	Northwestern University	None	None	None	None	None	None	None
William Hiatt	University of Colorado School of Medicine	None	None	None	None	None	None	None
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Todd Rosengart	Evanston Northwestern Healthcare	None	None	None	None	None	None	None

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